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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,931	01/26/2001	John H. Schneider	00.05.12.1	8223

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,931

Applicant(s)

SCHNEIDER ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 29,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-28, 30, 34, and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of appeal brief filed on January 27, 2004. The finality of the Office action dated September 23, 2003 is hereby withdrawn because the rejection did not include all the necessary prior arts. Examiner apologies for any inconvenience this might have caused. The rejections made in view of Mitchell et al. (US 5741433) in view of Vijayendran et al. (US 5173526); in view of Mitchell et al. and Vijayendran et al., and further in view of Walles et al. (US 4756844) ("Walles"); in view of Mitchell et al., Vijayendran et al., and Walles et al., and further in view of Garcia et al. (US 6436540 B1) as indicated in the Office action dated May 12, 2004 are maintained for the reasons of record therein.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 16, 17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US 5741433) ("Mitchell") in view of Vijayendran et al. (US 5173526) ("Vijayendran").

Mitchell teaches a controlled-release supplement coolant additive ("SCA") comprising a core containing the supplement coolant additive active component and a polymeric coating material encapsulating said core. See abstract; col. 3, lines 35 – 60. The reference teaches that the basic mechanism is that the pellet or table active diffuses through the polymeric coating material when water or water vapor from the outside the membrane wall penetrates through the polymeric coating and dissolve the

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water-soluble SCA encapsulated therein. See col. 5, lines 36 - 62. The reference further states, "a polymeric coating material having good moisture barrier properties greatly reduces the rate of dissolution of the SCA composition core, thereby providing more constant controlled release." See col. 5, line 63 – col. 6, line 2. The reference also teaches that water-insoluble film-forming polymers are suitable for the coating material. See col. 6, lines 2 – 5. See also the coating polymers tested in Tables 2 and 3 and the discussion in col. 1, line 1 – col. 8, line 25. For the SCA composition, the reference teaches alkali metal salts, borates, and sulphonates. See col. 3, line 60 – col. 4, line 16; instant claim 17. While the reference teaches the SCA may be in form of solid, granular or particulate form, having size of from about 1/32-3 inches. See col. 4, line 59 – col. 5, line 8. See instant claim 21.

Mitchell fails to teach polyurethane/vinyl hybrid polymer as used in the instant invention.

Vijayendran teaches that the polyurethane/vinyl hybrid polymer recited in the instant claims is a well-known protective coating material. See col. 1, lines 11 – 42; col. 9, line 9 – col. 11, line 34. The application of the polymer is taught in col. 6, lines 32 – 41. Examiner notes that the limitation following "prepared by" ending at "thereby form a urethane/vinyl hybrid polymer" is a process, which will not be given patentable weight in this product claim. See MPEP § 2113.

Given the general teaching in Mitchell that it is well known in the art to employ water-insoluble film-forming polymers having moisture barrier property to produce an encapsulated pellet or tablet having a water permeable membrane to reduce the rate of

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the release of the active ingredient, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Vijayendran for specific water-insoluble film forming polymers to produce a similar product with constant release of the active ingredient in aqueous environment.

2. Claims 18, 20, 23, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell and Vijayendran as applied to claims 16, 17, and 21 as applied above, and further in view of Walles et al. (US 4756844) ("Walles").

Mitchell and Vijayendran, discussed above, fail to teach using the second materials in the encapsulation as recited in the instant claims.

Walles teaches controlled-release composition having a water permeable membrane comprising submicron particles (anticoalescent agents), which encapsulate a liquid or solid active agent. See abstract. Aqueous colloidal silica is a preferred anticoalescent agent. See col. 5, line 44 – col. 7, line 17. The advantage of using anticoalescent to the membranes include the uniformity of the thickness of the membrane and reducing the amount of the membrane needed, reducing the time to form the membrane and agglomeration of the membrane material. See col. 6, line 55 – col. 7, line 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the encapsulated composition in the combined references by adding anticoalescent agents such as silica as motivated by Walles because of the expectation of successfully producing encapsulated materials with

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uniform membrane thickness, elimination of agglomeration of the membrane materials, and reduced amount and time of the coating material necessary to form the membrane.

3. Claims 19, 22, 24-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell, Vijayendran, and Walles, as applied to claims 16-18, 20, 21, 23, 34, and 35 as applied above, and further in view of Garcia et al. (US 6436540 B1) ("Garcia").

While Vijayendran teaches the addition of crosslinking agents, the combined references fail to teach using polyaziridines.

Garcia teaches that polyaziridines are conventionally used in crosslinking polyurethane/polyvinyl hybrid polymers. See Examples 1-4 and Table 1.

It is prima facie obvious to substitute equivalents for same purposes so long as the equivalency is recognized in the prior arts. See MPEP § 2144.06.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by substituting the crosslinking agents there with another conventionally used crosslinking agent polyaziridines, as suggested by Garcia, because of the expectation of successfully producing a composition of similar effects.

Response to Arguments

Applicant's arguments with respect to claims 16-28, 34, and 35 filed have been considered but are not persuasive.

Applicants argue that the combination of Mitchell and Vijayendran is not proper. Applicants specifically argue that the permeable property of a membrane wall made with

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the polyurethane-vinyl polymer dispersion and its “universal utility” in a capsule having controlled release properties.

In response to applicants’ argument that Mitchell teaches away from a using sticky/non-film former vinyl polymer, examiner notes that the Vijayendran polymer is not a sticky/non-film former vinyl polymer but a specific vinyl/polyurethane hybrid polymer for film forming properties.

Furthermore, applicants argue that the coating materials that are suitable for the Mitchell invention are limited to those that are “conventionally known in the art” at the time the Mitchell invention was made. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are made from the level or ordinary skill in the pertinent art **at the time the present invention was made.** Whether the Vijayendran was known to Mitchell at the time of the Mitchell invention is not a relevant factor.

Applicants argue that the flexible nature of the Vijayendran polymer does not suggest that the polymer renders a property “which does not protect a substrate”. Examiner respectfully disagrees with applicants argument that “the Vijayendran material does not protect the substrate from anything”. The function of a coating material inherently and essentially to protect the substrate from the environment. Controlled-release particulates Applicants’ examples of other “flexible” materials that cannot be used for controlled-release properties, i.e., steel, leather, paper, aluminum foil and rubber are unreasonable examples because they are not in polymer art. Vijayendran

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clearly teaches that the vinyl/polyurethane hybrid polymer is chosen because it is a good balance of protection and flexibility, which indicates that a complete protection property is not desired. Examiner reiterates that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants also argue that there is no suggestion in either Mitchell or Vijayendran to combine one with the other to produce the claimed subject matter. Examiner respectfully disagrees. It must be noted that the Mitchell reference teaches that permeability occurs even by transportation of water vapor through the membrane. See Mitchell, col. 5, lines 36-62. Mitchell also teaches that a polymeric coating material having good moisture barrier function is still desirable for constant controlled release of the core material in a capsule because such polymer greatly reduces the rate of dissolution of the active material. See col. 5, line 63 – col. 6, line 2.

It follows that the polymers with good moisture barrier function are useful for permeable coating. Examiner takes the position that the collective teaching of Mitchell and Vijayendran provide the expectation that even the Vijayendran vinyl/polyurethane polymer would be suitable as the coating material of the instant invention or the Mitchell invention, which provide the sufficient moisture barrier to provide both protection of the core material against the aqueous environment and the permeable property which is necessary to achieve the constant controlled release.

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Applicants also argue that Walles reference fails to teach the “greater than submicron” particle size of the second material. Examiner notes that applicants’ claim limitation read on a second material having a particle size from about 1 to about 15 microns. Given the broadest interpretation of the claims, about 1 micron reads on submicron.

Applicants also argue that the combined references fail to teach or suggest that the urethane/vinyl hybrid polymer can or should be cross linked. Examiner respectfully disagrees, as Vijayendran teaches using cross linking agent to retain urethane properties.

The combination of inter chain mixing and crosslinking of the vinyl phase allows retention of urethane properties. Compare polymer dispersion M made without acrylic multifunctional crosslinker with polymer dispersion L made with it. The combination of good inter chain mixing, oil soluble initiator, crosslinking of the vinyl polymer, and proper choice of urethane composition make it possible to prepare polymers with good properties even when the urethane is the minor component. Note the good properties of polymer dispersion N made at a 40% urethane 60% vinyl level.

See Vijayendran, col. 10, lines 58 – 69.

Applicants argue that applicants’ film is made by a different technique from the method known in the prior art, and further argues that applicants’ technique produces “a coating which obviously resists diffusion”, wherein the prior art method produces a film which resist diffusion. Examiner finds the argument unpersuasive because applicants are using the same polymer in Vijayendran as the film-forming polymer to coat the substrate. What is the difference between film and coat? Could the permeability the result of applying the same polymer in thinner film on the substrate? There is nothing in the claims to indicate whether

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the "enclosing membrane wall" is defined as film or coating. It simply requires the Vijayendran polymer, which would exhibit the same property applicants allege to have found.

Conclusion

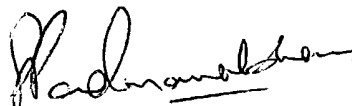
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
April 1, 2004


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER